K002310

OCT 2 5 2000

510(k) Summary
for
Meridian Medical Technologies Ltd
CardioBeeper ® CB12/12

Submitter

Meridian Medical Technologies Ltd
207 Airport Road West,
Belfast
BT3 9ED
Northern Ireland

Contact Name

Gerard Lynn
Manager, QA and Regulatory Affairs

Date of Application

26th July 2000

Device Name

Trade Name: CardioBeeper ® CB12/12

Classification Name: Telephone electrocardiograph transmitter and receiver per 21 CFR 880.2920

Substantially Equivalent Devices

The CardioBeeper ® CB12/12 is substantially equivalent to the CardioBeeper ® CB12-L (K965101).

Description of the Device

The CardioBeeper ® CB12/12 is a compact, hand-held, battery powered, personal transtelephonic ECG transmitter that is capable of transmitting a rhythm strip and a 12 lead ECG using three channels. The ECG data is frequency modulated onto three carriers which are transmitted simultaneously. This allows a complete transmission to be completed in approximately one third of the time required by the substantially equivalent device. The device has been designed to enable the user to transmit a 12 lead ECG to a central receiving station using acoustic coupling.

Intended Use of the Device

The CB12/12 is intended to condition an electrocardiographic signal so that it can be transmitted via telephone to a remote location. The CB12/12 is designed to be used by a patient to transmit a 12 lead ECG in real-time to a physician's office, hospital or other medical receiving centre.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 5 2000

Mr. Gerard Lynn
Manager, QA/RA
Meridian Medical Technologies Ltd.
207 Airport Road West
Belfast
BT3 9ED
Northern Ireland

Re: K002310
CARDIOBEEPER ® CB 12/12
Regulatory Class: II (two)
Product Code: DXH
Dated: July 26, 2000
Received: July 31, 2000

Dear Mr. Lynn:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act

for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K002310

Device Name: Meridian Medical Technologies Ltd, CARDIOBEEPER® CB12/12

Indications For Use:
The CB 12/12 is intended to condition an electrocardiographic signal so that it can be transmitted via telephone to a remote location. The CB 12/12 is designed to be used by a patient to transmit a 12 lead ECG and rhythm strip in real-time to a physician's office, hospital or other medical receiving center.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K002310

(Optional Format 3-10-98)

Prescription Use Only